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U.S. District Court  
Eastern District of MO

UNITED STATES DISTRICT COURT  
Eastern District of Missouri

**Deborah Toucheshawks**

Plaintiff

v.

United States of America

Acting U.S. Attorney General Matthew G. Whitaker

State of Missouri

State of Missouri Attorney General Eric Schmitt

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Case Number

Comes now plaintiff, **Deborah Toucheshawks**, and hereby requests the Court and the Clerk of the Court to enter the following request to end abuses by the Federal and State governments and respective agencies, to the Constitution and Bill of Rights of the United States of America. The Constitutional violations are *inter alia* to our Fourth, Fifth, and the Fourteenth Amendments as well as in violation of federal statutes *inter alia* Social Security Act 1935, The Medicare/Medicaid Act 1965 and multiple federal and state antitrust laws.

The following Brief is provided with a history and Legal Arguments in support of these factual allegations.

Plaintiff  
Pro Se:

This the 15<sup>th</sup> day of Feb 2019

Address:

**Deborah Toucheshawks**  
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Sullivan, Missouri 63080  
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35. *United States v. Mead Corp.*, 533 U.S. 218 (2001)
36. The Proxmire Act, 18 U.S.C. § 1091
37. *Kiobel v. Royal Dutch Petroleum Co.*, 621 F.3d 111, 173 (2d Cir. 2010)
38. *Washington v. Glucksberg*, 521 U.S. 702 (1997)

## History

We the people are guaranteed certain inalienable rights which are protected by our Constitution. Among these rights are the ability to make autonomous decisions regarding our health in the pursuit of life, liberty, and happiness. This statement is not to say the government must pay for our healthcare except as mandated by the Social Security Act, 1935, and the Medicare/Medicaid Act, 1965. These two Acts should be the full extent of having government involved in healthcare as is clearly indicated by the provision included in both:

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employees of any institution agency, or person providing health services to exercise any supervision or control over the administration or operation of any such institution agency or person. U.S. Code, Title 42, Chapter 7, Subparagraph XVII, §1395 – Prohibition against Federal Interference.

Justice James Clark McReynolds made it clear by establishing a legal precedent when he wrote: “Obviously, direct control of medical practice in the states is beyond the power of the federal government.” *Linder v. United States*, Page 268 U.S. 18. (1925).

Therefore the recent attacks on “opioid” based medications make no sense. Government officials typically must rely on “expert” testimony as they have little to no medical training. The lack of medical education is apparent when it comes politicians attempting to establish policies ignoring the proper treatment of Chronic Pain Syndrome (ICD-10 code G89.4 ) or Intractable Pain Disease, injuries or diseases which currently have no medical cures.<sup>(1)</sup>

March 2008, during the 110th Congress, the Senate Subcommittee on Crime & Drugs Hearing, Chaired by Senator Joe Biden Jr. (D-DE), received written testimony from Dr. Alex DeLuca, FASAM, MPH, regarding the “Gen Rx: Abuse of Prescription and OTC Drugs.”<sup>(2)</sup> His testimony, *Why Untreated Chronic Pain is a Medical Emergency*, went into great detail explaining how undertreated or untreated pain is a “universal complicator.” Unrelieved pain worsens all co-existing medical or psychiatric problems through the stress mechanisms (leading to chronic cardiovascular stress, hyperglycemia which both predisposes to and worsens diabetes, splanchnic vasoconstriction leading to impaired digestive function and potentially to catastrophic consequences such as mesenteric insufficiency). Consequences of untreated and inadequately-treated pain are often profound decrements in family and occupational functioning and iatrogenic morbidity consequent to the very common misidentification of pain patients as drug seekers. Dr. DeLuca went on to predict if undertreated or denied pain medications, suicides in this population would increase to twice the national average.<sup>(3)</sup>

The following year, September 2009, researchers, Torrance N, Elliott AM, Lee AJ, Smith BH, the National Institute of Health published the report: *Severe chronic pain is associated with increased 10 year mortality. A cohort record linkage study*. Their research determined the death risk from poorly controlled moderate to severe chronic pain is 68% greater than for individuals suffering from cardiovascular disease. Additionally, the risk of death within this population is 49% greater than all other causes combined.<sup>(4)</sup>

The National Institute of Health and the Department of Veterans Affairs confirmed in 2010 the seriousness of injuries or diseases with no current medical cure with a report utilizing medical records and survey answers from veterans. This data from the 1999 Large Health Survey of Veterans was designed to determine the impact of veterans experiencing various levels of

pain. Unsurprisingly, the resulting data demonstrated veterans with severe pain were more likely to die by suicide than patients experiencing none, mild, or moderate pain.<sup>(5)</sup> By 2015, the deaths of veterans from the Department of Veterans Affairs policies to deny all legitimate pain medications was even more pronounced with the following results.<sup>(6)</sup>

Department of Veterans Affairs (VA) conducted analyses of national data that have found the following:

1. In fiscal year 2013, patients prescribed less than 90 morphine equivalent daily dose accounted for 95.8% of the sample and 85.7% of overdose/suicide-related deaths.
2. In two sets of fiscal years – 2010-2011 and 2013-2014 – opioid discontinuation was not associated with overdose mortality but was associated with increased suicide mortality.

With the evidence piling up, members of Congress began to recognize something was sketchy with the Centers for Disease Control (CDC) proposed draft guidelines in 2015. Before the CDC's publication, March 2016, the honorable Jason Chaffetz (R-UT), Chair of Committee on Oversight & Government Reform, wrote to the CDC director, Tom Frieden, MD.<sup>(7)(8)(9)</sup> In the letter dated December 18, 2015, Congress requested information about the process of drafting these guidelines and the names of those individuals involved in providing the recommendations. In this letter, Mr. Chaffetz acknowledges the proposed guidelines would be insufficient to treat those suffering from chronic pain by recognizing the American Cancer Society Network and other national organizations reservations.

Christopher W. Hansen, President, American Cancer Society Network, wrote on October 1, 2015, "we cannot endorse the proposed guidelines in any way and suggest suspending

the process until methodological flaws are corrected and more evidence is available to support prescribing recommendations.

Congress was not the only Federal agency objecting to the CDC's proposed guidelines. The Food and Drug Administration, Sharon Hertz, director of the FDA's Division of Anesthesia, Analgesia and Addiction Products, stated the evidence cited to support the guidelines was "low to very low and that's a problem." Additionally, this agency which normally plays a lead role in setting guidelines for prescription drugs the FDA "did have an opportunity to look at the product and comment," but otherwise was not involved in its development according to Ms. Hertz.<sup>(8)</sup>

The FDA, however, was not the only Federal Agency to express concerns. "This is a ridiculous recommendation from my perspective. Very low quality of evidence, yet a strong recommendation. How do you possibly do that?" asked Richard Ricciardi, Ph.D., of the Agency for Healthcare Research and Quality. I would be remiss and I'm certain so would many of my government colleagues if I didn't go back to my director and say there's a report coming out of the CDC that has very low quality of evidence and there's a strong recommendation. That's an embarrassment to the government."<sup>(8)</sup>

Despite the fact the CDC guidelines were not completed or published, President Barack Obama signed into law the "Consolidated Appropriation Act of 2016" which forced the Department of Veterans Affairs to adopt it as official policy when VA doctors treat veterans suffering from chronic pain.<sup>(10)(11)</sup> With federal agencies and the public expressing outrage for the "low to very low evidence" based guidelines, Congressional leaders coerced medical professionals within the VA medical system to abandon his/her Hippocratic Oath by adopting and publishing nationwide February 2017, the VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain, 2016, Version 3.0.<sup>(12)</sup>

What many do not realize, is President Donald Trump signed into law June 6, 2018, the VA Mission Act which forces civilian doctors to abide by the same deadly policies without any provisions protecting civilian patients. Section 131 directs civilian doctors specifically to adhere by the VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain, 2016, Version 3.0 or face financial sanctions for failure to comply.<sup>(12)(13)</sup>

Since the publication of the CDC guidelines, the Federal governments and its entities (*inter alia* CDC, DEA, FDA, HHA, VA) have implemented a series of policies and legislative acts, besides being illegal, are in direct violation of the Fifth Amendment. Specifically: no person shall “be deprived of life, liberty, or property, without due process of law.”

Additionally, with the publication of the CDC guidelines, Federal policies and legislative acts, numerous state governments and their entities (medical boards, licensing boards, law enforcement agencies, *et cetera*) have implemented policies and legislative acts in direct violation of the Fourteenth Amendment. Specifically: “No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.”

These states include but are not limited to the following: Alaska, Arizona, Colorado, Connecticut, Delaware, Florida, Hawaii, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and West Virginia.<sup>(14)</sup>

At present forty-nine states have prescription monitoring program laws. In forty-eight of the states, law enforcement agencies and/or judicial authorities are specifically allowed access to privileged medical information contained in the prescription monitoring program database. Only Nebraska recognizes the importance of our Fourth Amendment rights protecting our right to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures.<sup>(14)</sup>

The VA's National Suicide Data Report, June 18, 2018, indicates suicide rates increased for both Veterans and non-Veterans, underscoring the fact that suicide is a national public health concern that affects people everywhere.<sup>(15)(16)</sup> These numbers have continued to rise within the veterans' population since the VA began denying legitimate pain medications in St. Cloud, Fargo and Minneapolis, Minnesota in 2012.<sup>(17)</sup> This report once again confirms the 2008 Senate testimony by Dr. Alex DeLuca: "suicides will increase to 2x the national average among Chronic Pain Patients being limited or denied pain medications."<sup>(3)</sup>

The CDC released "Suicide rising across the US: More than a mental health concern," June 2018. This report reveals suicide rates have increased by 30% nationwide with over 54% of the people resorting to this final drastic measure had no history of mental health issues.<sup>(18)</sup> These unnecessary deaths confirm the NIH report indicating individuals with undertreated or untreated pain conditions has a 68% greater chance of death than a person suffering from cardiovascular disease. Also supporting these acts of desperation need not have occurred is the 2010 report by the NIH and the VA stating: "the resulting data demonstrated veterans with severe pain were more likely to die by suicide than patients experiencing none, mild, or moderate pain."<sup>(4)(5)</sup>

This information has been available for years before the publications of the CDC guidelines, the VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain, 2016,

Version 3.0, and the numerous federal and state policies and laws implemented since. These policies represent a “Clear and Present Danger” to the American people and our Constitution guaranteeing all Americans that no person shall “be deprived of life, liberty, or property, without due process of law.”

## Legal Argument

### Legal Precedent Filing Pro Se

In Supreme Court decision *Johnson v. City of Shelby* the Court makes it clear neither *Twombly* nor *Iqbal* nor the federal pleading rules, require “*pro se*” plaintiffs to set forth the legal theory supporting the asserted claim for relief. *Johnson v. City of Shelby*, Miss., 743 F.3d 59, 62 (5th Cir. 2013). *Bell Atlantic Corp. v. Twombly* (2007). *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

### Disparate Impact

If these laws and policies have not been a planned attack against Americans and veterans with Chronic Pain Disease or Intractable Pain Disease, the policies from a falsified crisis remain a Death Sentence for far too many. These policies illustrate the definition of a **Disparate Impact:**

“Title VII of the United States Civil Rights Act Disparate treatment is one kind of unlawful discrimination meaning unequal behavior toward someone because of a protected characteristic (e.g., race, gender or disability).”

These protected classes of people are collateral damage. We are caught up in the wide net the government has cast to combat what they call the opioid epidemic. We are being treated like addicts when in reality we are not; although we did not choose a life of constant pain, but this is who we are now: fighting for our right to live. Unintentional discrimination at first has now become Disparate Action, intentional discrimination. These government agencies now know about the legitimate chronic pain community being adversely affected; yet they persist with these deadly policies and propaganda destroying any chance for a quality of life promised by our Constitution.

## **Bill of Rights – Upheld by the Supreme Court**

In a similar fashion, the courts have upheld “[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury;” violations to any of the our Constitutional Rights constitutes irreparable injury to the United States of America and for future generations of our children. Am. Broad. Cos., Inc. v. Wells, 669 F. Supp. 2d 483, 489 (D.N.J. 2009) (quoting Elrod v. Burns, 427 U.S. 347, 373 (1976); see also Citizens United for Free Speech II v. Long Beach Twp. Bd. of Comm’rs, 802 F. Supp. 1223, 1237 (D.N.J. 1992)).

## **Fourth Amendment Violations**

In particular many of these policies target an individual’s right to privacy, which the courts have upheld in numerous cases with statements such as; “searches conducted outside the judicial process, without prior approval by judge or magistrate, are per se [implicitly] unreasonable under the Fourth Amendment” Katz v. United States, 389 U.S. 347 (1967). With policies and laws creating prescription drug monitoring programs (PDMP) Americans no longer have a reasonable expectation of privacy for our health records.

Recent developments allow for government’s invasion of privacy to extend into the civilian world (against both veterans and civilians) as medical providers are threatened and coerced into compliance to provide sensitive data. The law signed by President Trump, June 2018, is named, The VA Mission Act 2018 and Section 131; “...would also require VA to implement a process to make certain that community care providers have access to available and relevant medical history of the patient, including a list of all medication prescribed to the veteran as known by VA. This section would require contracted providers submit medical records of any care or services furnished, including records of any prescriptions for opioids, to VA in a timeframe and format specified by VA. VA would be responsible for the recording of those

prescriptions in the electronic health record and enable other monitoring of the prescription as outlined in the Opioid Safety Initiative... If VA determines that a community provider is not complying with the Opioid Safety Initiative, **VA is authorized to refuse authorization of care by such provider and direct their removal from the community care network.”**

At what point is a patient's expectation for privacy diminished beyond "irreparable harm" as the Fourth Amendment "guard[s] against searches and seizures of items or places in which a person has a reasonable expectation of privacy," United States v. Ziegler. 474 F.3d 1184 (9th Cir., January 30, 2007). As was stated recently: "[b]y reviewing doctors' prescribing information, the DEA [and other state & federal agencies] inserts itself into a decision that should ordinarily be left to the doctor and his or her patient," Oregon Prescription Drug Monitoring Program v. United States Drug Enforcement Administration, Case No. 3:12-cv-02023-HA, D. Oregon (February 11, 2014).

### **Supreme Court Rulings: Fifth and Fourteenth Amendments**

"Avoiding intolerable pain and the indignity of living one's final days incapacitated and in agony is certainly... involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment. At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State." Casey, 505 U.S. at 851.

"After considering the fundamental constitutional questions resolved by Roe, principles of institutional integrity, and the rule of stare decisis, we are led to conclude this: the essential

holding of Roe v. Wade should be retained and once again reaffirmed." Casey, 505 U.S. at 851 Roe v. Wade, 410 U.S. 113 (1973).

"Constitutional protection of the woman's decision to terminate her pregnancy derives from the Due Process Clause of the Fourteenth Amendment. It declares that no State shall "deprive any person of life, liberty, or property, without due process of law." The controlling word in the case before us is "liberty." Although a literal reading of the Clause might suggest that it governs only the procedures by which a State may deprive persons of liberty, for at least 105 years, at least since *Mugler v. Kansas*, 123 U.S. 623, 660-661 (1887), the Clause has been understood to contain a substantive component as well, one "barring certain government actions regardless of the fairness of the procedures used to implement them." *Daniels v. Williams*, 474 U.S. 327, 331 (1986).

As Justice Brandeis (joined by Justice Holmes) observed; "[d]espite arguments to the contrary which had seemed to me persuasive, it is settled that the due process clause of the Fourteenth Amendment applies to matters of substantive law as well as to matters of procedure. Thus all fundamental rights comprised within the term liberty are protected by the Federal Constitution from invasion by the States." *Whitney v. California*, 274 U.S. 357, 373 (1927) (Brandeis, J., concurring). "[T]he guaranties of due process, though having their roots in Magna Carta's '*per legem terrae*' and considered as procedural safeguards 'against executive usurpation and tyranny,' have in this country 'become bulwarks also against arbitrary legislation.'" *Poe v. Ullman*, 367 U.S. 497, 541 (1961)

## **Due Process**

The Due Process Clause "...is a promise of the Constitution that there is a realm of personal liberty which the government may not enter. We have vindicated this principle

before. Marriage is mentioned nowhere in the Bill of Rights and interracial marriage was illegal in most States in the 19th century, but the Court was no doubt correct in finding it to be an aspect of liberty protected against state interference by the substantive component of the Due Process Clause in *Loving v. Virginia*, 388 U.S. 1, 12 (1967) (relying, in an opinion for eight Justices, on the Due Process Clause). Similar examples may be found in *Turner v. Safley*, 482 U.S. 78, 94-99 (1987); in *Carey v. Population Services International*, 431 U.S. 678, 684-686 (1977); in *Griswold v. Connecticut*, 381 U.S. 479, 481-482 (1965), as well as in the separate opinions of a majority of the Members of the Court in that case, *id.*, at 486-488 (Goldberg J., joined by Warren, C. J., and Brennan, J., concurring) (expressly relying on due process), *id.*, at 500-502 (Harlan, J., concurring in judgment) (same), *id.*, at 502-507 (White, J., concurring in judgment) (same); in *Pierce v. Society of Sisters*, 268 U.S. 510, 534-535 (1925); and in *Meyer v. Nebraska*, 262 U.S. 390, 399-403 (1923).

*Roe v. Wade*, however, may be seen not only as an exemplar of *Griswold* liberty but as a rule (whether or not mistaken) of personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection.” *Casey*, 505 U.S. at 851.

**Obergefell v. Hedges, 576 U.S. No. 14-556 (2014)** “(1) The fundamental liberties protected by the Fourteenth Amendment’s Due Process Clause extend to certain personal choices central to individual dignity and autonomy, including intimate choices defining personal identity and beliefs. See, e.g., *Eisenstadt v. Baird*, 405 U. S. 438, 453; *Griswold v. Connecticut*, 381 U. S. 479, 484–486. Courts must exercise reasoned judgment in identifying interests of the person so

fundamental that the State must accord them its respect. History and tradition guide and discipline the inquiry but do not set its outer boundaries.”

### **To Live Life without Governmental Interference**

“The ability to participate equally in the economic and social life of the Nation has been facilitated by each individual’s ability to control their lives.” See, e.g., R. Petchesky, *Abortion and Woman’s Choice* 109, 133, n. 7 (rev. ed. 1990).

### **Workable & Within Constitutional Rights**

The request for an Injunction against Federal and State government and entities therein (CDC, DEA, FDA, etc.) are in no sense proven “unworkable,” see *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528, 546 (1985), representing as it does a simple limitation beyond which a state law is unenforceable and the required determinations fall within judicial competence.

### ***Skidmore* deference**

The CDC guidelines do not carry the force of law. Therefore, the guidelines published by the Centers for Disease Control are not binding as the basis for any state and/or federal statute requiring enforcement by any state and/or federal agency IE: the Drug Enforcement Agency, targeting doctors in the treatment of nonmalignant pain (Chronic Pain Conditions which currently have no known medical cure). Nor do the CDC guidelines carry the force of law or have any scientific bearing to be applied and/or enforced by any entity or medical provider within the Department of Veterans. *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)

*United States v. Mead Corp.*, 533 U.S. 218 (2001) explicitly reaffirms *Skidmore* and reiterates deference to agency interpretations that do not have statutory authority resulting from a

rule-making process as long as the process establishes "the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position."

### **Genocide Defined**

The very essence of these policies, especially the limitations placed on accessibility of legitimate pain medications by insurance companies and new regulations within the Medicare/Medicaid covered medications, targets the weakest among our population. Those at greatest risk include: the elderly, cancer patients, the disabled, veterans, minorities, and the lower socioeconomic groups unable to secure high priced doctors or insurance policies enjoyed by the elitists and politicians making these laws and policies.

The Proxmire Act, 18 U.S.C. § 1091 is very clear on the subject:

"Whoever, whether in time of peace or in time of war and with the specific intent to destroy, in whole or in substantial part, a national, ethnic, racial, or religious group as such...

1. kills members of that group;
2. causes serious bodily injury to members of that group;
3. causes the permanent impairment of the mental faculties of members of the group through drugs, torture, or similar techniques;
4. subjects the group to conditions of life that are intended to cause the physical destruction of the group in whole or in part."

*Kiobel v. Royal Dutch Petroleum Co., 621 F.3d 111, 173 (2d Cir. 2010)*

### ***Glucksberg dicta***

Supreme Court Justices O'Connor, Ginsburg, Breyer, Stevens, and Souter stated clearly that patients have a right to pain relief and that state laws should not inhibit access to palliative

care. They based the right in the “inherent dignity of the person.” *Washington v. Glucksberg*, 521 U.S. 702 (1997)

Justice Breyer uttered the key phrase that is relevant for our current set of circumstances wherein state and federal laws and regulations are restricting physician and patient access to opioids. “Were the legal circumstances different – for example, were state law to prevent the provision of palliative care, including the administration of drugs as needed to avoid pain at the end of life–then the law’s impact upon serious and otherwise unavoidable physical pain (accompanying death) would be more directly at issue.” Therefore the restrictions are *de facto* (because physicians are afraid to prescribe for any number of reasons, from fear of prosecution to lack of adequate education) and *de jure* (the direct result of new laws and regulations).

Justice Breyer’s separate opinion also stated that a strong argument could be made for the existence of a “constitutional right to die with dignity” which “at its core” would involve “personal control over the manner of death, professional medical assistance, and the avoidance of unnecessary and severe physical suffering.” Moreover, “were state law to prevent the provision of palliative care, including the administration of drugs as needed to avoid pain on the end of life – then the law’s impact upon serious and otherwise avoidable physical pain (accompanying death) would be more directly at issue.” Does this statement not make more sense for those individuals desiring to continue living life with family and friends, giving back to his/her communities, to be provided medications necessary to avoid pain or at least minimize the effects of uncontrolled pain from diseases and injuries with no medical cure?

“No rational argument can be made to justify limiting the right to avoid “unnecessary and severe physical suffering” only during the last moments, days, or weeks of life. If beneficiaries

of this right to palliative care have a core interest in dying with dignity, surely they also have a core interest in living with dignity until they actually die. Lawyers who would oppose such an argument would have to prove that physicians can pinpoint the exact moment “dying” begins, in order to start the clock on when pain medication would become legally available.”

Justice Breyer’s words “infringe directly upon...the core interest of dying with dignity,” which involves “medical assistance, and the avoidance of unnecessary and severe physical suffering.” “Avoiding intolerable pain and the indignity of living one’s final days incapacitated and in agony is certainly “at the heart of [the] liberty . . . to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life.” (Casey, 505 U.S. at 851.) (*Revisiting the constitutional right to Palliative Care*. Katherine Irene Pettus, Ph.D. Pain Policy & Palliative Care. May 10, 2012)

### **Exhausting all Administrative Procedures for Redress of Grievances**

State and Federal Government attorneys first line of defense in getting this complaint dismissed will most assuredly be a claim and numerous legal precedents indicating the plaintiffs have not exhausted all Administrative Procedures for Redress of Grievances.

Over the past several years, the same as Congressman Jason Chaffetz (R-UT)<sup>(7)</sup>, numerous groups and individuals have completed the limited “open comments” periods provided by the CDC, the Food & Drug Administration (FDA), the Department of Health and Human Services (HHS) to name but a few. Even with all the comments and presentations depicting factual data to the harm being done to over 111 million Americans with Chronic Pain or Intractable Pain Disease (25 million with injuries or disease with no current medical cure), the HHS declared in 2017, the opioid crisis as a “public health emergency” complete with graphics

and a “5-Point Strategy to Combat the Opioid Crisis.”<sup>(19)</sup> <https://www.hhs.gov/opioids/about-the-epidemic/index.html>

The data provided in the graph on the HHS page is highly misleading to the point of being falsified to create panic among the public with little or no medical or addiction training.

Besides these numbers not actually adding up, the CDC admitted in 2016 (again in 2017 & 2018) the number of deaths related to opioids were inflated primarily but not exclusively due to polypharmacy deaths being counted two or more times.<sup>(20)(21)(22)(23)</sup> IE: An autopsy report indicates heroin, alcohol and cocaine in the body. This would be reported as three separate opioid related deaths for one autopsy. One of the sources cited in the HHS claims is the National Center for 2016 Health Statistics (NCHS) however the HHS Claims are in direct conflict with the 2016, NCHS’ report written by Margret Warner, Ph.D.: “Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2010–2014.”<sup>(24)</sup> The report was quietly provided to members of Congress in December 2016 showing that illegal drugs like heroin, cocaine and fentanyl are responsible for more drug overdose deaths in the United States than opioid pain medication after their original report to Congress earlier in the month indicating the need for the proposed guidelines.<sup>(24)</sup>

One study, which covered overdoses from 2010 to 2014, by the CDC and FDA found that many “overdose” deaths involved multiple drugs or alcohol. Over three-quarters of the deaths involving oxycodone and hydrocodone, for example, involved other substances such as cocaine and methamphetamines. Alcohol was involved in 15 percent of all drug overdoses.

Another major fallacy in the reporting of deaths related to synthetic opioids; these agencies attempt to minimize the number of deaths from the synthetic opioid, methadone (4,545 methadone related deaths 2011-2016 behind heroin 4,571 & cocaine 5,070 – both illegal

drugs).<sup>(25)(26)(27)</sup> Meanwhile these laws and policies continue to allocate billions in providing methadone and the latest diverted prescribed drug with a 66% failure rate: the synthetic opioid Suboxone.<sup>(28)</sup> All of this to fix the non-existent opioid crisis while denying millions of veterans and Americans legitimate pain medications for Chronic Pain Disease and Intractable Pain Disease.

### **What is the source of CDC's science?**

The problems within the CDC have been apparent for many years prior to the release of the now "infamous" guidelines. Scientists, with multiple doctorates have complained for years "[t]here are now so many bureaucrats and midlevel managers who control "the Message" at CDC in Atlanta who are making decisions on subjects way out of their sphere of knowledge." With individuals operating out of his/her depth of training and experience begs to question: who is providing the CDC its message? Unfortunately, the same scientists who have been ignored know exactly why true and factual research is failing to reach the people. "We have been told that CDC is responding to HHS, and HHS is responding to the White House...it all sounds as if politics is trumping the science."<sup>(29)</sup> Specific recommendations from this report include but have been ignored by all governmental agencies and politicians include: "The CDC should work to align agency practices with its solid scientific integrity policy."<sup>(30)</sup>

### **Dr. Richard "Red" Lawhern**

Richard "Red" Lawhern Ph.D. has long been an advocate for Chronic Pain Patients speaking out to the harms associated with the misapplication of the guidelines. One of his latest efforts at addressing grievances from millions of Americans occurred September 25, 2018, at the HHS Inter Agency Task Force for Best Practices in Pain Management.<sup>(31)</sup> His testimony can be viewed online at: <https://youtu.be/Kn1WoRlrCKc>

Dr. Lawhern's dedication in educating elected officials, through an incalculable number of hours poring over reams of research, undoubtedly makes him one of the most highly admired advocates for patients. Even so, Dr. Lawhern and others have been unsuccessful in obtaining any response on the merits of their petitions from the CDC, FDA, NIDA and HHS/CMS. Dr. Lawhern submitted a formal complaint against the CDC on the grounds of gross misbehavior, malfeasance, and fraud in its development of the 2016 opioid prescription guidelines, to the department of HHS Office of the Inspector General, on August 25, 2018. On November 1, 2018, he and over a hundred endorsers also submitted a petition urging HHS/CMS suspension of Medicare Part D rule changes authorizing mandated soft and hard safety edits by insurance providers as of January 1, 2019. Neither organization has responded to these petitions and complaints in any way. Dr. Lawhern has also been informed in a follow-up telephone conversation, the HHS/OIG will not respond to his formal complaint. He was advised to submit a Freedom of Information Act requesting all department documents pertaining to the investigation; even then, he should expect that no Office Inspector General (OIG) finding will be entered into the records for at least six months following the petition.<sup>(31)</sup>

These organizational failures to act in good faith may reasonably be regarded as a deliberate and intentional policy of stonewalling and denial of redress for grievances. As a result of this stonewalling, the following comments by Dr. Richard Lawhern are provided as evidence that the Chronic Pain Community and Professional Advocate Organizations have exhausted all Administrative Procedures for Redress of Grievances.<sup>(31)</sup>

(1) Managed medical exposure to opioid therapy is rarely associated with substance abuse in pain patients. Published CDC data reveal no cause-and-effect relationship between rates of physician prescriptions of opioids, versus rates of overdose-related

mortality. NONE. The idea that over-prescribing caused our US opioid “crisis” is an urban myth invented out of thin air by CDC and DEA policy makers who didn’t do their homework. Published demographics of addiction and chronic pain also contradict this urban myth. Chronic pain patients are almost never abusers, even if they become dependent on opioids for pain management.

(2) Ample data also establish that medically managed opioid therapy is safe and effective for millions of pain patients for long periods. Though there are few long-term double-blind trials due to drop-outs of patients randomized to placebo, the Centers for Medicare and Medicaid Services acknowledge that ~1.6 million patients (plus possibly similar numbers under private insurance) have been maintained on doses exceeding the 90 morphine milligram equivalent daily dose safety threshold of the Guidelines, often for periods of several years. CDC has demonstrated no elevated mortality statistics among these patients. Seniors, in fact, have the lowest level of opioid overdose-related mortality from all sources, of any age group.

(3) Publication of a massive systematic outcomes review in June 2018 by the US Agency for Healthcare Research and Quality reveals that there are no proven-safe alternative treatments that may safely be substituted for analgesic or anti-inflammatory therapy. No trials for non-invasive, non-pharmacological therapies have progressed beyond small-scale Phase I trials as additions (adjuncts) to usual therapy. The state of precision in the nearly 5,000 published trials reports is so abysmal that only 218 survived a careful quality review. These therapies may have a role as additions to medical therapy, but not as replacements. And they are most certainly not “preferable” as claimed by the CDC.

(4) The CDC Guideline writers ignored well-established literature on the metabolism of opioids in the human liver. Due to natural genetic variations in the expression of six liver enzymes, some people are poor metabolizers and others “hyper” metabolizers for up to 90% of all medications. As confirmed by recent AMA resolutions, the high natural variability in minimum therapeutic dose levels between patients makes any effort to standardize dose levels or duration completely inappropriate on the part of legislators or regulators.

(5) The only ethical response to this policy debacle must be an immediate withdrawal of the fatally flawed CDC document to correct its many biases, errors, distortions and omissions. State regulations and laws based on the document must also be repealed. The DEA must also be put on notice that in the absence of patient complaints or a documented pattern of hospital admissions or fatalities, it is grossly inappropriate to investigate individual doctors solely on the basis of the volume of medications that they prescribe. By contrast, it is essential that disproportionate patterns of opioid shipments to rural zip codes by major corporate distributors be investigated to detect the few remaining pill mills.

In addition to Dr. Lawhern along with many other professionals and patients being outspoken regarding the harsh outcomes of denying pain medications to patients when various entities have misinterpreted and misapplied the CDC guidelines, the American Medical Association (AMA) finally stepped up in November 2018.<sup>(32)</sup>

### **American Medical Association**

The AMA has approximately 217,490 members and is one of the largest lobbying groups for medical professionals nationwide. At an interim meeting, the AMA adopted a series of

resolutions calling for restraint and even a complete reversal for parts of the CDC Guidelines.

The resolution read as follows: <sup>(32)</sup>

RESOLVED that our AMA affirms that some patients with acute or chronic pain can benefit from taking opioids at greater dosages than recommended by the CDC Guidelines for Prescribing Opioids for chronic pain and that such care may be medically necessary and appropriate.

RESOLVED that our AMA advocate against the misapplication of the CDC Guidelines for Prescribing Opioids by pharmacists, health insurers, pharmacy benefit managers, legislatures, and governmental and private regulatory bodies in ways that prevent or limit access to opioid analgesia.

RESOLVED that our AMA advocate that no entity should use MME thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guidelines for Prescribing Opioids.

### **Requested Actions of the Court**

With all due respect, the plaintiff respectfully requests of the Court:

1. Respectfully request of the Court that all Americans be allowed to join this litigation against the state of **Missouri** and the United States of America by submitting a "Motion to Join" with this case number. This request is essential considering the multitude of innocent Americans suffering from these archaic policies and everyone deserves the opportunity to redress grievances against the government. These

policies, the CDC opioid prescribing guidelines version 1.0 , the VA/DoD opioid safety initiative version 3.0, the VA Mission Act 2018, and all Federal and State legislation stemming from the same are in violation of the Fifth and Fourteenth Amendments as the acts perpetrated by the agencies named are discriminatory in nature and harmful (potentially deadly) to the American people and to veterans who suffer from Chronic Pain Disease or Intractable Pain Disease (*inter alia* the elderly, cancer patients, the disabled, minorities, and impoverished communities throughout America).

2. By and through the order of the Court, the DEA will stop persecuting licensed medical professionals and his/her patients by accessing state and federal databases which contain private medical information protected by Health Insurance Portability and Accountability Act of 1996 thereby violating the Fourth Amendment.
3. Pharmacy employees will no longer be allowed to use ‘profiling’ to determine who may or may not receive controlled medications. These employees do not have access to the patients’ medical records. These “policies” have been implemented by CEOs and crisis legislators indoctrinated by media hysteria regarding drug overdose deaths caused by illicit opioids and other drug use; not the legal medicinal use prescribed by appropriately trained physicians. In essence, these are a reincarnation of discriminatory laws of the late 19<sup>th</sup> century except these policies target patients: the elderly, cancer patients, disabled, minorities, especially African Americans, and the lower socioeconomic consumers. Our pharmacists and technicians have too many years working diligently to perfect their skills to suddenly be placed in a position of judge, jury, and executioner.

4. The Administrative Procedure Act gives the Judiciary Branch oversight on government agencies (VA, CDC, FDA, DEA, *et cetera*), to ensure the policies and rules they make are in the best interest for all Americans. These policies are violations of our Bill of Rights and International Treaties signed and ratified by the United States thus providing Jurisdiction within the Federal Courts to protect American citizens from abuses by these agencies, the Constitutional violations and criminal acts by an overzealous Legislative Branch.

Respectfully

Plaintiff  
Pro Se: \_\_\_\_\_

This the \_\_\_\_\_ day of \_\_\_\_\_ 2019

Address:

**Deborah Toucheshawks**  
11410 Moss Oak Rd  
Sullivan, Missouri 63080  
573 268 1646

## Certificate of Service

I, **Deborah Toucheshawks**, the plaintiff, certify that a true and correct copy of the forgoing complaint was served on the following persons by placing the documents in the United States Postal Service with sufficient postage affixed this \_\_\_\_\_ of \_\_\_\_\_ 2019.

United States of America  
Acting U.S. Attorney General Matthew G. Whitaker  
C/O Assistant Attorney General for Administration  
U.S. Department of Justice  
Justice Management Division  
950 Pennsylvania Avenue, NW  
Room 1111  
Washington, DC 20530

State of Missouri  
State of Missouri Attorney General Eric Schmitt  
Missouri Attorney General's Office  
Supreme Court Building  
207 W. High St.  
P.O. Box 899  
Jefferson City, MO 65102  
573-751-3321

Respectfully

Plaintiff  
Pro Se: \_\_\_\_\_

This the \_\_\_\_\_ day of \_\_\_\_\_ 2019

Address:  
**Deborah Toucheshawks**  
11410 Moss Oak Rd  
Sullivan, Missouri 63080  
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